

### Remarks/Arguments

The Office Action dated May 14, 2008 has been received and carefully studied.

The Examiner objects to the drawings under 37 C.F.R 1.83(a). The Examiner states that the first and second drainage paths must be shown or cancelled from the claims. The Examiner states that Figure 1 is a schematic and that Figures 2 and 6 disclose alternate embodiments of the variable check valve, however these figures only show one possible path.

The applicant cannot understand how the drawings are unclear. Figure 1 shows a representative system, and clearly shows 2 drainage paths; supine mode flow path 27 and upright mode flow path 25. Upright mode flow path 25 has a variable check valve 26. This valve, as seen in Figure 1, has a single input and output. Figures 2 and 6, as disclosed in the specification, illustrate embodiments of that variable check valve. Both Figure 2 and Figure 6 show a single input and a single output, as these figures correspond to variable check valve 26 of Figure 1. These figures are clearly shown and described so that one skilled in the art would be very clear as to the operation and structure of the invention.

The Examiner rejects claims 1-7 under 35 U.S.C. §102(e) as being anticipated by Madsen et al (U.S. Patent No. 6,384,160). The Examiner states that Madsen teaches a system for regulating the flow of CSF from the brain comprising an implantable controller in the form of an anti-siphon shunt valve 80 having first and second drainage paths 86 and 88,

wherein controller 80 directs the flow of CSF into said first or second drainage path in response to the inclination of the individual. The Examiner states that this direction of flow is accomplished via a closed-loop feedback control system wherein orientation sensor 104 provide orientation data as an input to control 106, which in turn sends control signals to actuator 108 which adjusts the height of an adjustable barrier.

The present claim requires that the "controller directs the flow of said cerebrospinal fluid into said first or second drainage paths in response to the inclination of said individual". Madsen does not have this feature. Madsen describes a system where fluid enters both pathways, however, it typically only passes through the path of less resistance. Madsen also describes an anti-siphon valve which has little or no resistance when the patient is recumbent, but has a "high fluid flow resistance that is greater than the fluid flow resistance of the high resistance valve 90". Column 6, lines 44-46. In other words, the resistance of the anti-siphon valve changes as a function of the patient's orientation. This change in resistance makes the high resistance path a more viable fluid path for CSF, and thus fluid starts passing through that pathway. However, the fluid is not directed from one path to another by a controller as recited in the claims; rather fluid passes through the second path as a result of the automatic change in the resistance of the anti-siphon valve in response to the patient's change in orientation. This change in path is completely independent of the controller in the Madsen device, and would work in this manner even if Madsen did not have a controller to adjust the anti-siphon valve. Thus, Madsen does not disclose a system

whereby the controller directs the flow of CSF based on the patient's inclination.

Furthermore, the Madsen device works in a fundamentally different way than the present invention. This device uses the second drainage path only when "the cerebral spinal pressure increase[s] to dangerous levels while the patient is standing up". Column 6, lines 47-48. The first fluid path is the primary path and is adjustable via an actuator that "adjusts the adjustable barrier in the anti-siphon device in order to provide optimal treatment conditions for patient". Column 7, lines 15-17.

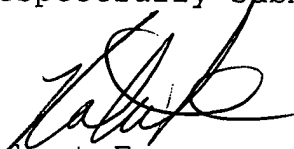
In other words, one fluid path is used when the patient is supine and this path has a cracking pressure that is adjustable based on the patient's orientation. The other fluid path has a much higher fixed cracking pressure and is only used when CSF pressure reaches a dangerous level.

In contrast, the present invention uses a fixed low resistance path when the patient is supine, and a variable resistance path when the patient is upright or nearly upright. In other words, both paths are used in normal operation, and it is the upright path which is variable. The claims have been amended to clearly recite these differences.

The Examiner rejects claims 8-11 under 35 U.S.C. §103(a) as being unpatentable over Madsen et al. In view of the amendment to independent claim 1, the remaining dependent claims are believed to be in condition for allowance.

Reconsideration and allowance are respectfully requested  
in view of the foregoing.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Robert Frame', written over the typed name.

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